

The Maryland Board of Pharmacy

Public Meeting Minutes — April 22, 1998

1. Introductions - Recusals

President David Russo called the meeting to order at 8.45 A.M. In attendance were David Russo, President, W. Irving Lottier, Secretary, Commissioners Stanton Ades, Wayne Dyke, Dorothy Levi, Barbara Jackson, and Rev. William Johnson; Board Counsel, Paul Ballard; Board staff, David Denoyer, Pam Owens, Norene Pease, Sharon Cornish, and Tamarra Banks.

Guests present include:

Robert Vlk, Purdue Frederick Company
Nathan Gruz, Melvin Rubin, Pharmacists
Kathleen Jaeger, Hyman Phelps, McNamara representing Barr Laboratories
Mimi Azrael, Maryland Women's Law Center
Jack Freedman, Division of Drug Control
Tony Tomesello, PEAC
Ray Love, University of Maryland, School of Pharmacy

President Russo requested that any member of the Board with a conflict of interest relating to an item on the agenda should notify the Board at this time. There were no conflicts reported.

2. Approval of Minutes

Mr. Denoyer requested that corrections be made at the suggestion of Commissioner Jackson, namely that the record of attendance was in error by omitting the names of Commissioner's Jackson and Johnson. Commissioner Levi made a motion to accept the minutes as amended which was seconded by Commissioner Jackson. The minutes were unanimously approved as amended by the Board.

3. Executive Director's Report

A. Personnel Status Report

Norene Pease introduced Sharon Demory-Cornish, the new administrative specialist who is supervising the licensing Unit. Ms. Cornish has met with the Licensing Committee and now working on the licensing and examination processes.

Ms. Pease reported that the Board is in the process of interviewing for a new office secretary III to support Board functions including disciplinary and Board and Task Force meetings.

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B. Toxsense - Board Media Campaign

Ms. Pease reported that the Board met with MMA during the March meeting and reviewed the Toxsense media campaign. A follow-up meeting to discuss the fund raising aspect of the campaign was held with the Oversight Committee on April 2, 1998. The University of Maryland's Development Officer, Arla Altman, will coordinate with MMA and with the School of Pharmacy's capital fund raising campaign. Fund raising efforts will be complimentary to ensure that both programs have an appropriate development strategy to meet planned needs. MMA has prepared for Ms. Altman a summary of solicitation efforts to date. MMA will also prepare an estimate of future financial needs for the media campaign that are consistent with the public relations plan to be presented to the Oversight Committee.

Ms. Levi asked whether the informational packets are out to pharmacies? Ms Pease reported that the posters are being printed and will be mailed in the near future.

C. District II (NABP/AACP) Meeting - October 22-25 1998

Mr. Denoyer reported that Ms. Pease, Dean Knapp and Dr. Love had met and discussed the meeting agenda, which will focus on pharmacists participation in emerging health care settings such as managed care and large retail chain pharmacies.

Mr. Denoyer requested Board member participation in the meeting development. Fund raising for the meeting is proceeding. About \$10,000 is needed for the meeting to supplement registrations. Dr. Telang at Howard University is the treasurer for the Region, and will assist in collecting funds from donors.

D. ELTP Training June 6, 1998

The electronic transfer program enables the Board to access national examination scores via a specially equipped computer located in the Board Office. NABP is contemplating re training Board personnel in the use of this system given that there have been changes in the software since the program was initiated several years ago. NABP is contemplating funding the cost of meals and housing if the Board will pay for transportation to and from Chicago. Ms. Pease requested the Board's approval to send Ms. Cornish or Ms. Thomas to the training. The Board approved the use of travel funding for this purpose.

4. Board Counsel's Report

Mr. Ballard introduced Ms. Mimi Azrael from the Women's Law Center of Maryland and

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stated that the group had recently held a conference on medical privacy issues.

Ms. Azrael commented that she read Board minutes and agenda on the Internet and complimented the Board on its pro-active stance with regard to the protection of patient medical records. In addition, she provided a case from Massachusetts involving Elensys, which is being challenged in a class action suit. Mr. Ballard will review the matter for relevance in our proceedings.

She also reported concern that her family's prescriptions from a previous pharmacy (used two years ago) were transferred to a new pharmacy without her authorization when her former pharmacy was recently closed. She said that she subsequently began receiving letters from an unknown source that appeared to be her present pharmacist insinuating that she or a family member was non-compliant with taking a specified medication. She expressed concern that specific medication information about her family was conveyed to another party that she did not believe should have access to the information without her consent. She further stated that she was concerned that the transfers of her prescriptions to CVS tied her to the Elensys company which had recently been criticized in an article in the Washington Post.

The Board determined that the source of the letter to Ms. Azrael was probably the McKesson Company or its subsidiary. The Board directed staff to invite both Ms. Azrael and representatives of McKesson to an upcoming Board meeting to discuss this situation in the near future.

Ms. Azrael volunteered to work with the Board to examine existing law pertaining to the continuity and confidentiality of medical records under various pharmacy record scenarios. Board Counsel reminded the Board that existing law relating to the confidentiality of medical records, over which the Board does not have jurisdiction, was intended to cover physicians, dentists, podiatrists and their agent's medical records. It was not originally designed to take pharmacy medical records into consideration and should possibly be revised. Ms. Azrael recommended including in Board regulations language ensuring that patients receive notification that their medical records are being transferred to another pharmacy and provide a mechanism for patients to refuse acceptance of the transfer.

President Russo, Mr. Ballard and Ms. Azrael discussed the laws under current consideration in the US Senate. These proposals may pre-empt State law, potentially damaging state's ability to prevent information sharing for inappropriate purposes. Ms. Azrael graciously offered to update the Board in this area.

5. Guest Presenter

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6. Committee Reports

A. Licensing Committee - Wayne Dyke

1. Examination Schedule - Proctors Needed for June 22, 23, 1998

Mr. Dyke reported that the Committee met on April 8th. The closing date for NABPLEX is May 8th. The testing window is June 22nd - August 15th, 1998. The Board application cut-off is May 15th. On April 29th the Licensing Committee will meet to review applications. The examination dates will be June 22 & 23. Law examination is on June 22. A new procedure for checking candidates into the examination was discussed and will be implemented. Corrections in the mailing to examinees entitled Pharmacist's Licensure Examination have been made and revised copies will be mailed to each applicant along with notification of approval to take the examination. A letter will also go to applicants reminding them of the oral English competency requirement and encouraging licensure candidates to take this part of the examination as quickly as possible.

In addition, a letter is being mailed to renewal candidates informing them that the CE extensions would only be granted in extreme cases. CE credits must be completed at the time of renewal and it is unlikely that an extension will be granted.

2. Committee Schedule for Review of Examination Candidate Applications

See Above

3. Reciprocity

Mr. Dyke introduced 15 candidates, three (3) pending English competency: Emmanuel Akala, Kenneth Blythe II, Danielle Brown, Judy Crain, Russell M. Ruchta, Mildred Crandon-Enyi, Elizabeth Kostin, Sheila D. Patel, Sanjay Mason, Shirish A. Patil, Caroline Osilesi, Heinrich M. Rosser, Gloria Coombs, Joel Langberg and Willie C. Walter.

Mr. Dyke made a motion that was seconded by Barbara Jackson to approve all candidates for licensure with the following candidates approved contingent upon receipt of certification of passing oral English competency: Gloria Combs, Joel Langberg and Willie C. Walter. The motion was unanimously approved.

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4. Multistate Pharmacy Jurisprudence Examination (MPJE)

Ms. Pease reported that the NABP wishes to mail potential questions for the MPJE to a designated member of the Board for review. Mr. Ades offered to review the questions.

5. Continuous NAPLEX Testing Window

NAPB contacted the Board to see if it would support a continuous window of opportunity for candidates to take the NAPLEX. The Board agreed to support this action. Ms. Pease reminded the Board that in the near future, the Licensing Committee should consider how the laboratory examination could be offered more frequently since the MPJE would become computerized in June 1999 and would likely be available continuously shortly thereafter.

The committee rescheduled the next licensing meeting for 10 am on Wednesday, May 27th.

B. Legislative Committee

1. Legislative Status

- a. SB 412/HB 1062 “Consumer Protection - Drug Storage Shipment Safety”

Ms. Owens reported that these bills passed and were awaiting the signature of the Governor. Ms. Owens distributed copies of the final version.

- b. HB 1094 “Physician Assistants - Physicians Delegated Prescriptive Authority”

Ms. Owens reported that this bill failed on third reader in the House.

- c. HB 1187 “Collaborative Disease State Management”

Ms. Owens reported that this bill failed on third reader in the House.

- d. SB 352/HB 803 “Project Reserve Funds”

Ms. Owens reported that SB 352 died in Committee. HB 803 passed the House and was

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amended in the Senate. It died because the House did not have time to consider it again after the Senate amendments.

- e. HB 383 “Health Occupation Boards - Disclosure of Information”

Ms. Owens reported that this bill died in Committee.

- f. SB 782 “Home Health Advisory Committee”

Ms. Owens reported that this bill passed and is awaiting the signature of the Governor.

- g. HB 1408 “Drug Substitution Notification”

Ms. Owens reported that this bill died in Committee.

- h. SB 363/HB 444 “Physical Therapy - Topical Agents”

Ms. Owens reported that SB 363 passed the Senate but received an unfavorable report from the House Environmental Matters Committee. HB 444 died in Environmental Matters.

2. Strategic Planning Meeting Report - April 15, 1998

The Strategic Planning Group met on the May 15th to review the 1998 Legislative Session with respect to the Collaborative Drug Therapy Management and Medication Administration bills. The group decided to formulate two work groups, one a coalition of Pharmacy Associations and EPIC to examine non-Board issues such as lobbying and fund-raising. Membership in the group includes but is not limited to: Bill Popomaronis, Murhl Flowers, David Moore and Arnold Clayman. A second group will examine options for strategy development for next year. Ray Love will talk with Dean Knapp regarding designating a pharmacist from the School to take the lead with this group. Melvin Rubin will inquire if Phillip Weiner will also participate in this group.

The next meeting will be held on Wednesday, May 27th at 8:00a.m.

Regulation Update - Code of Conduct

Mr. Ades asked for comment on the new regulation. The comments were as follows:

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(I) Under .01C: The first suggestion was to delete the dependent clause that discusses collaborative practice.

The second suggestion was to either delete this provision entirely or change the phrase “therapeutically equivalent drug” to “therapeutical alternative.”

(ii) Under .02: The suggestion was to add the word “fraudulently” and delete the phrase “for services or products not provided.” As it is currently written, a pharmacist could be disciplined for accepting a contract fee under a capitation system. This was not the intention of the Pharmacy Practice Committee.

(iii) Under .03B: The first suggestion was to add a phrase making it clear that a pharmacist is allowed to disclose to an authorized person but that the pharmacist is not required to disclose to an unauthorized person.

The second suggestion was to add Division of Drug Control to B(iv) and to add a phrase making it clear that any of these individuals had to be acting within their capacity as government agents before a pharmacist should disclose.

The third suggestion was to add a new (viii) to §B which makes clear that researchers and educators are authorized persons in some situations.

(iv) Under .05: The suggestion was to revise the reporting provision to allow a pharmacist to report suspected drug use or abuse to PEAC instead of directly to the Board.

(v) Under .06: The first suggestion was to delete §C entirely.

The second suggestion was to delete the word “sex” from §D and change it to “sexually intimate act.”

(vi) Under .08: The first suggestion was to delete the dependent clause in §A requiring pharmacist to dispense when failure to dispense would cause death, serious physical injury or serious long-lasting injury.

The second suggestion was to change §B to delete the “professional judgement” defense and to instead hold a pharmacist to “generally accepted professional standards.” Mr. Ballard provided model language for this change.

Ms. Owens will draft the suggested changes for review by the Pharmacy Practice

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Committee. The Practice Committee will make recommendations to the full Board at the next Board meeting and the full Board will vote at that time.

Electronic Transmission of Prescriptions

Mr. Denoyer will revise the draft regulations to include review of concerns raised in meetings and publications of the Federal Drug Enforcement Agency. He will include the revisions in a subsequent Board packet.

Experience Required for Licensure by Reciprocity

Mr. Denoyer reported that this Chapter 15 proposal is now final, and provides for applicants to pass a written test and the English competency exam.

Chapter 19 Parenteral/Sterile Enteral Compounding Amendments

Ms Levi suggested that comments from MSHP should be solicited relating to the provisions relating to IV solution preparation. Mr. Denoyer will request such input and report the recommendations to the Pharmacy Practice Committee and to the Board.

PEAC Update

Mr. Tommasello reported that the CE program at the MPHA meeting was well received. The program to educate chain store managers about the work of PEAC and how to identify and report potential drug and or alcohol misuse amongst pharmacists will be implemented in the near future.

Mr. Tomasello will send a white paper to the Board for review. The paper addresses the concerns of the PEAC relating to identifying pharmacists in need of assistance to avert drug and alcohol misuse.

Mr. Tomasello also noted that PEAC sister organizations in other states have implemented a mechanism for the anonymous reporting of cases under surveillance by the PEAC to the Board. This process keeps the Board informed about the number, type and severity of cases under review by PEAC and provides information about the incidence of drug and alcohol misuse among pharmacists who seek treatment from PEAC in the State. He suggested that PEAC is moving in the direction of providing a fuller description of cases and case load to the Board in the future.

PEAC is close to incorporation as a private non-profit entity. Ms. Pease inquired if Board

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staff should begin the process of writing a small procurement request for proposal (RFP) for competitive bids to receive Board funding which has been provided to PEAC in the past via memorandum of agreement with the University of Maryland, School of Pharmacy. Mr. Tomasello indicated that Board staff should begin the preparation of such a RFP.

The annual PEAC retreat is scheduled in July and a Board member usually attends. PEAC will ensure that information on the retreat is made available to members of the Board and its staff.

Pharmacy Practice Committee

Commissioner Ades reported from the - April 15, 1998 meeting with Commissioners Ades, Levi and Jackson and staff Pam Owens and David Denoyer. Mr. Ades reported that the next meeting is scheduled for May 6, 1998 and will focus on several of the matters discussed at this Board meeting, including the Code of Conduct and the new electronic transmission concerns.

The Practice Committee reviewed its agenda for action items and discussed consultation to prisons, schools and health departments as an opportunity to emphasize the pharmacist expertise in the consultation area. We should solicit the input of school, prison and health department nurses and pharmacists for the Committee meeting.

In addition, the subject of pharmacist consultation in these settings should be promoted in our newsletter.

The second item discussed was security of and in pharmacies. Ms. Levi suggested that the practice committee should address not only physical security of the drugs, but also security of the prescription records. Mr. Ades noted that this item is related to Ms. Azreal's concerns about the security of medical records. The committee will consider revising the pharmacy closure regulations.

A third item discussed was potential prescription blank regulations. The laws in Titles 12, 21, 27 and regulations will be copied for a future meeting.

The topic of Pharmacy Support Personnel was discussed. Mr. Ades suggested that this item should be discussed in a larger forum, rather than in the Practice Committee. The Board could send a letter to interested parties and organizations. Ms. Pease suggested that we might use a consultant to work with the technician task force.

The topic of long term care facility supplier pharmacies was discussed. Mr. Ades noted

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that this item is already being referred to a separate task force as suggested in the April newsletter.

Budget Committee - Redirect Unspent F.Y. 98 Appropriation

Ms. Banks discussed with the Board two options for redirecting unspent funds from the FY1998 budget for other projects. She suggested enhancing the distribution of information via the media campaign by purchasing advertising space on billboards throughout the State. Another option was purchasing law books from MPHA for pharmacies and/or new licensees.

Mr. Ballard expressed concern that Michie Company had a contract with the State and a copyright for producing written copy for all State laws. He suggested that staff determine if MPHA has to sell the law book. Ms. Banks stated that she would continue to research these issues. If MPHA can produce the law book at a price that is less than Michie and they have rights to the material, Mr. Ballard did not foresee a problem with purchasing law books from MPHA.

F.Y. 2000 Budget Development

Ms. Banks requested that Board members advise her if they have recommendations for special Board projects for FY2000. She will discuss ideas with the Board in June.

Per Diem Tracking System

Ms. Banks introduced to the committee an activity report form. Forms have been provided to Board members. The log Book for all forms will remain at the Board office. Committee Chairs or staff are to ensure that the form is completed for each official meeting of the Board. The form will provide documentation for expenses incurred for Board activities reflected in the budget and can be balanced against expense reports signed by the Secretary or Executive Director.

B. New Inquiries*

Stephen J. Allen, R.Ph. - Dr. Allen discussed the use of automated drug distribution, using a Pyxis machine in an on-site skilled nursing facility. He noted that this would occur in a hospital, but in a portion licensed as a long term care facility. The proposed automated system would tie the profile of the patient into the dispensing of the drugs.

The system would allow drugs to be available at the point of use, while mandating that the

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pharmacist is available to review the order.

He noted that some of the devices are now providing limited selections of drugs for emergency use. This proposed system would provide most regular dosed of drugs. Mr. Allen noted that the use of technicians, automation, and computers makes the trend of automated point-of-use systems in hospitals inevitable, and that this trend will certainly continue to long-term-care.

Mr. Allen commented that even with an individually packaged unit-dose system, when the staff manipulates the drug, systems are not foolproof, but the new system is better than many existing systems.

Question from Ms. Levi: Was it your intent to replace the unit dose cart?

Mr. Allen: Yes, this would replace the cart. However, access to the medication is limited .

President Russo commented that the Board would review the proposal and thanked Mr. Allen for his time. Mr. Ades commented that a “field trip” for Board members may be useful. Mr. Allen suggested that he may be able to arrange for a demonstration.

IV Emergency Drug Kits - Board of Nursing Work Group Discussion

Mr. Denoyer reviewed an April 16th meeting with the Board of Nursing/Pharmacy/Licensing and Certification workgroup studying the issue of Registered Nurses carrying drugs for home health care intravenous emergency care. Stanton Ades and Paul Ballard attended the meeting.

The proposal would allow drug kits to be distributed to the home health agency sites if a prescriber authorizes the distribution. Pharmacies would prepare and label the kits, the contents of which would be determined by a joint committee of the Boards of Pharmacy and Nursing. Controlled drugs would not be included. (Heparin and saline are the main focus of this initiative).

Mr. Ades moved to develop regulations to enable this proposal. Ms. Jackson seconded and the motion to develop regulations and submit a notice of regulatory development passed unanimously.

Adjournment

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President Russo adjourned the meeting at approximately 12:00.

Respectfully Submitted,

W. Irving Lottier, Jr., Secretary